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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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LEGAL DEPARTMENT
INCYTE GENOMICS, INC.
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EXAMINER	
HARRIS, A	
ART UNIT	**PAPER NUMBER**
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 19

Application Number: 09/208,619
Filing Date: December 8, 1998
Appellant(s): Incyte Genomics, Inc.

P. Ben Wang
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed May 25, 2001..

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the

pending appeal is contained in the brief. Therefore, it is presumed that there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existence of any related appeals and interferences.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows: the rejection of claim 17 under 102(e) as being anticipated U.S. Patent number 5,876,991 (filed February 21, 1997) is withdrawn.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 17, 18 and 32 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

Maarse, A. Et al. "Identification of the essential yeast protein MIM17, an integral mitochondrial inner membrane protein involved in protein import." FEBS Letters, vol. 349, no. 2 (1994), pp. 215-221.

Ryan, K. Et al. "SMS1, a High-Copy Suppressor of the Yeast mas6 Mutant, Encodes an Essential Inner Membrane Protein Required for Mitochondrial Protein Import." Molecular Biology of the Cell, vol. 5 (May 1994), pp.529-538.

Harlow and Lane. "Antibodies: A Laboratory Manual." Pp. 96-99. 1988. Cold Spring Harbor Laboratory.

Amino acid databases, Accession numbers P39515 and Q02310.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 U.S.C. § 112

Claims 17 and 18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 17(c and d) is broadly drawn to a purified polypeptide comprising an amino sequence selected from a biologically-active fragment and immunologically active fragment of the amino acid sequence of SEQ ID NO:1. This claim is drawn to a polypeptide fragment that contains a small number of amino acid residues that is less than the 172 amino acids of SEQ ID NO:1, hence the claim is drawn to amino acid residues that minimally contain only portions of SEQ ID NO:1. Absent evidence to the contrary, each of the fragments is deemed to be an incomplete polypeptide, likewise it is clear that the partial sequences would not be the claimed polypeptide consisting of amino acid sequence of SEQ ID NO:1, nor function as the full length polypeptide is alleged. Thus, the claims are drawn to a large genus of molecules. In the case of small identified amino acid residues claimed with open language, the genus of polypeptides comprising only a partial sequence encompasses a variety of subgenera with widely varying attributes. The specification discloses only the structural features of one species, the polypeptide sequence of SEQ ID NO:1. The specification lacks information to lead one of skill in the art to understand that the applicant had possession of the broadly claimed invention at the time the instant application was filed.

Claim Rejections - 35 U.S.C. § 102

Claim 17 is rejected under 35 U.S.C. 102(b) as being anticipated by Accession Numbers P39515, Q02310, Maarse et al. (FEBS Letters 349:215-221, 1994, Reference #5 on IDS) and Ryan et al. (Mol. Biol. Cell 5:529-538, 1994, Reference #4 on IDS). Accession

Numbers P39515, Q02310, Maarse et al. (see page 217, Figure 1B) and Ryan et al. (see page 532, Figure 3) disclose a purified polypeptide comprising an amino acid sequence that is a biologically-active fragment of the amino acid sequence of SEQ ID NO:1.

Claim Rejections - 35 U.S.C. § 103

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Accession Numbers P39515, Q02310, Maarse et al. (FEBS Letters 349:215-221, 1994, Reference #5 on IDS) and Ryan et al. (Mol. Biol. Cell 5:529-538, 1994, Reference #4 on IDS, in view of Harlow and Lane (Antibodies, A Laboratory Manual, Cold Spring Harbor Laboratory, 1988). As previously discussed, the aforementioned references teach a purified polypeptide comprising a biologically-active fragment of amino acid sequence SEQ. ID. NO. 1. Accession Numbers P39515, Q02310, Maarse et al. (FEBS Letters 349:215-221, 1994, Reference #5 on IDS) and Ryan et al. (Mol. Biol. Cell 5:529-538, 1994, Reference #4 on IDS) do not teach polypeptides comprised in a composition such as an adjuvant contained with saline, mineral oil or aluminum hydroxide.

Harlow and Lane teach the pharmaceutically acceptable diluent of pH neutral, phosphate buffered saline solution for the storage of polypeptides and the production of

adjuvants. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to formulate a pharmaceutical composition comprising a carrier/excipient and the polypeptides of claim 1 in order to store the polypeptides in solution for the purpose of making an adjuvant. One of ordinary skill in the art would have been motivated to store the polypeptides in saline because Harlow and Lane teach that these components are necessary when producing an effective adjuvant. Moreover, one of ordinary skill in the art would have had a reasonable expectation of success in placing the polypeptides of claim 17 in a pharmaceutically acceptable carrier such as saline because this protocol is a standardly used immunological technique described in basic antibodies manual such as Harlow and Lane.

Because pharmaceutically acceptable carriers such as sterile saline solution and phosphate-buffered-saline solution were well known in the art, one of ordinary skill would have known how to formulate a pharmaceutical composition comprising a carrier/excipient and the instantly claimed polypeptides.

When the claim is directed to a product, the preamble or intended use is generally nonlimiting if the body of the claim is directed to an old composition and the preamble merely recites a property inherent in the old composition. [*Kropa v. Robie*, 88 USPQ 478, 480 - 81 (CCPA 1951); see also MPEP 2111.02]. Thus, art which reads on a compound may also be applied to pharmaceutical compositions consisting essentially of said compound and a suitable pharmaceutical carrier.

It has been held by the Court that a compound and a carrier are obvious, if it is obvious in the art to utilize a carrier with related compounds. See In re Rosicky, 125 USPQ 341 (CCPA 1960).

(11) Response to Argument

Claim Rejections - 35 U.S.C. § 112

Appellants summarize case law, which states the requirements necessary to fulfill the written description requirement of 35 U.S.C. 112, first paragraph., as well as the Patent and Trademark Office's "Guidelines for Examination of Patent Applications Under the 35 U.S.C. Sec. 112, para. 1" on page 4 of the Brief. The essential disagreement appears to be the interpretation of what meets the written description standards set forth by the Office.

Appellants assert that the amino acid sequence of SEQ ID NO:1 is explicitly disclosed in the specification and that the specification describes the chemical and structural characteristics of the polypeptide designated as SEQ ID NO:1 (HuTIM17). Likewise, the specification further states that the polypeptide and fragments thereof can be produced by either recombinant means or by chemical synthesis and antibodies can be produced specific to HuTIM17. Appellants find that "...there is no need to explicitly list the sequences of the numerous possible fragments" Appellants argue that methods for determining the biological activity of HuTIM17 are set forth in the specification.

The Appellants have not shown that the invention encompassing the recited fragments is in their possession. There are no sufficient details and relevant identifying characteristics of

these biological and immunological fragments which would provide evidence that Applicant was in possession of the claimed invention. There is no identification or description of specific amino acid fragments that should be designated as "biologically-active" and "immunologically-active". There is no disclosed correlation between the function, structure or some combination of such characteristics presented within the specification that clearly recognize that Applicants were in possession of the claimed invention. Appellants have yet to disclose in full and exact terms wherein lies the biological and immunological activity. Appellants claim embodies an infinite number of species which may or may not be representative of the genus, SEQ ID NO:1. There is no satisfactory disclosure of the claimed fragments' ability to embody the attributes of biological activity and immunological activity. Variant species, such as Appellants fragments cannot be embraced by the adequate written description of a genus. Nor can written description requirements be achieved by disclosing only one species of a number of species. The biological and immunological activity of the claimed fragments is essential and critical to the Appellants' invention and must be supported by the disclosure of the subgenera and the possession of each.

Claim Rejections - 35 U.S.C. § 102/ 35 U.S.C. § 103

Appellants summarize the art rejections of record on pages 6 and 7 of the Brief. The essential disagreement appears to be that the prior art references applied for 102 and 103 are not anticipatory, nor *prima facie* obvious, respectively. Appellants also note that the requirements for transmembrane domains in membrane proteins are well known in the art and the amino acids referenced by the Examiner would be immediately recognized by one of skill in the art as simply being too short to serve as transmembrane domains.

Accession Numbers P39515, Q02310, Maarse et al. (FEBS Letters 349:215-221, 1994, Reference #5 on IDS) and Ryan et al. (Mol. Biol. Cell 5:529-538, 1994, Reference #4 on IDS), all evidence amino acid fragments that clearly anticipate Appellant's claimed invention of biologically-active fragments that are imported into the inner mitochondrial membrane. Appellants have not identified what amino acids should be excluded, nor included within the framework of biologically-active fragments. There is no evidence presented by Appellants that is contrary to the disclosed fragments' ability to be imported into the inner mitochondrial membrane. Both, Maarse and Ryan state that proteins from which the fragments are derived are essential to the protein import machinery of the mitochondrial inner membrane. Notwithstanding, it would be *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to formulate a composition comprising a carrier/excipient and the polypeptides of claim 17.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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August 3, 2001

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